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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,089	03/16/2005	David McMurray Garrison	2860 (203-3387PCTUS)	7097

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EXAMINER	
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ART UNIT	PAPER NUMBER
4116	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/528,089	GARRISON ET AL.	
	Examiner	Art Unit	
	RONALD J. HUPCZEY, JR.	4116	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 March 2005* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/16/2005, 12/02/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. In response to the Preliminary Amendment filed on March 16, 2005, claims 1-19 are pending.

Information Disclosure Statement

2. Applicant is informed that the references cited in the information disclosure statements (IDS) filed on 12/02/2005 are lined through by the Examiner, because it is the duplicate of the same references cited in the other IDS filed by Applicant. It has been placed in the application file, but the information referred to therein has not been considered as to the merits.

Specification

3. The attempt to incorporate subject matter into this application by reference to the switch assembly described in a US Patent Application titled "Stepped Printed Circuit Board for Snap-Domes in Medical Devices" is ineffective because the incorporation fails to list the application serial number with which it is associated with. Appropriate correction is required for the reference to be incorporated into the current application.

Drawings

4. The drawings are objected to under 37 CFR 1.83(a) because they fail to show 102a (distal end), 120 (tool tip), 164 (button), 160 (snap-dome) and 116 (button) as described in the specification. Any structural detail that is essential for a proper

understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). In addition, the drawings are also objected to as failing to comply with 37 CFR 1.84(p) (5) because they include the following reference character(s) not mentioned in the description: 112 and 128 in Figure 13. Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

5. Claim 2 is objected to because of the following informalities: Examiner believes the word "light" appearing in the claim is intended to be "tight" as previously mentioned in claim 1. Examiner notes that the claim will be interpreted as including "... the fluid tight dielectric seal ...". Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 16, 17 and 19 are rejected under 35 U.S.C. 102(b) as being anticipated by Broadwin et al (US Pat. No. 4,931,047).

Regarding claim 16, Broadwin et al discloses an electrosurgical instrument containing a handpiece (handpiece **16**) and a tool member (tool **20**) at least partially supported within the handpiece, the tool member having a proximal end adapted to engage an acoustic vibrator, having a distal tool tip (see col. 4, lns. 8-10), partially defining an aspiration channel (passageway **26**) and being formed from an electrically conductive material (see col. 5, lns. 56-59). Broadwin et al further discloses a conductive member (metallic contactor **58**) connected to a source of electrosurgical energy (RF energy) functioning to deliver electrosurgical energy to the tool tip (tip **22**). Additionally, Broadwin et al discloses a gas supply channel (annular passage **34**) connectable to an external supply and distally placed adjacent to the tool tip. Broadwin et al further discloses an electrode positioned to interact with the gas supplied and connected to the electrosurgical energy.

Regarding claim 17, Broadwin et al discloses the electrode (tool **20**) to extend through the gas channel (annular passage **34,** see figures 3 and 6).

Regarding claim 19, Broadwin et al discloses a switch assembly (dome switch **52**, **54**) capable of delivering electrosurgical energy to the tool member and electrode.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Broadwin et al (US Pat. No. 4,931,047).

Regarding claim 18, Broadwin et al broadly discloses the electrode to be adjustable within the gas supply channel. The disclosure by Broadwin et al of the threaded engagement of the tool **(20)** with the connecting member **(38)** is capable of acting as such (see col. 4, lns. 8-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the removable engagement can function to allow for axial movement within the channel resulting in an adjustable electrode position.

11. Claims 1-10 and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Broadwin et al (US Pat. No. 4,931,047) in view of Schoenman et al (US Pat. No. 6,402,748 B1).

Regarding claim 1, Broadwin et al discloses an electrosurgical instrument containing a handpiece (handpiece **16)** and a tool member (tool **20)** at least partially supported within the handpiece, the tool member having a proximal end adapted to engage an acoustic vibrator, having a distal tool tip (see col. 4, lns. 8-10), partially defining an aspiration channel (passageway **26)** and being formed from an electrically conductive material (see col. 5, lns. 56-59). Broadwin et al further discloses a nosecone

(housing **18**, handpiece **16**) positioned about a distal end of the handpiece and a proximal end of the tool member, the nosecone including an inner housing and a switch assembly (switch **50**). Additionally, Broadwin et al discloses the switch to control delivery of electrosurgical energy to the tool member (see from col. 4, ln. 59 to col. 5, ln. 6). Broadwin et al fails to disclose a fluid tight dielectric seal functioning to seal the switch assembly from an outer surface of the nosecone. Schoenman et al discloses a handheld electrosurgical device containing a seal about the housing and switch assembly contained on the housing. Schoenman et al further discloses the seal to be elastomeric and formed of a dielectric material (see col. 5, ln. 18-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include such a seal as disclosed by Schoenman et al on the electrosurgical instrument of Broadwin et al to allow for an electrosurgical instrument with a sealed switch. The idea of a sealed electronic switch is old and well known and is commonly utilized to prevent electrical shock and to increase user safety.

Regarding claims 2-6, Broadwin et al fails to disclose a fluid tight dielectric seal or any structural description of such a seal about the electrosurgical instrument. Regarding claim 2, Schoenman et al discloses the overmolding of a dielectric seal from an electrically insulative elastomeric material (see col. 5, ln. 18-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize such a material as disclosed by Schoenman et al to form the fluid tight seal disposed on the electrosurgical instrument of Broadwin et al. The idea of a sealed electronic switch is old and well known and is commonly utilized to prevent electrical shock in the art.

Regarding claim 3, Schoenman et al discloses the insulative material to be overmolded about the housing. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that such an insulative material disposed on the housing of the Broadwin et al electrosurgical instrument would provide for an electrically insulative outer housing as claimed. Regarding claim 4, Schoenman et al discloses the outer housing (seal **150**) capable of being custom formed to any electrosurgical device. Schoenman et al further discloses the capability of the seal to be molded to allow for various dimensions and sealing means (see col. 8, lns. 4-30). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to utilize a seal design disclosed by Schoenman et al in conjunction with the electrosurgical instrument disclosed by Broadwin et al to allow for an outer housing sealingly engaging the distal end of the handpiece. The combination is readily allowable due to the disclosure of Schoenman et al of the various molding techniques and adaptability of the seal material. Regarding claims 5 and 6, Schoenman et al discloses the seal to be sealable by a method of friction fitting (see col. 8, lns. 17-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include the seal disclosed by Schoenman et al with the electrosurgical instrument of Broadwin et al to allow for a sealed electrosurgical instrument. It is old and well known in friction fits of seals to include one or more protrusions to enable the seal to tightly engage the surface. The disclosure by Schoenman et al readily allows for such a feature to be included in the molding.

Regarding claim 7, Broadwin et al discloses a flue (housing **16**) positioned about partially about the tool member, an outer surface of the tool member (tool **20**) and the inner member of the flue (housing **16**) defining an irrigation fluid delivery channel (annular passage **34**, see col. 3, lns. 55-59).

Regarding claim 8, Broadwin et al discloses an inner housing and a flue together as a single piece. Schoenman et al discloses the ability of an outer housing (seal **150**) to be overmolded over any variety of electrosurgical devices. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the inner housing and flue assembly of Broadwin et al in conjunction with the overmolded outer housing (seal **150**) of Schoenman et al would be capable of forming a recessed structured allowing a seal to be formed between the associated structures. The combination is readily allowable by the various molding and attachment techniques of sealing materials disclosed by Schoenman and would provide a sealed device to prevent electrical shock.

Regarding claim 9, Broadwin et al discloses an irrigation conduit (irrigation tubing **32**) for delivering irrigation fluid to the irrigation fluid delivery channel (annular passage **34**) and an aspiration conduit (tube **29**) for receiving fluid from the aspiration channel (passageway **26**).

Regarding claim 10, Broadwin et al discloses the tool member (tool **20**) to include a couple member (connecting member, see col. 4, lns. 8-20) and a removable tip (tip **22**). Broadwin et al further discloses the coupling member to have a distal end capable

of releasing the tool tip and the proximal end capable of releasing an acoustic vibrator (see col. 4, lns. 8-20).

Regarding claim 13, Broadwin et al discloses a channel capable of passing a supply of gas (annular passage **34**) and an electrode (tool **20**) positioned to interact with the supplied gas. Broadwin et al further discloses a first end of the channel adaptable to an external supply source and for a second end to be placed adjacent the distal tool tip (tip **22**).

Regarding claim 14, Broadwin et al discloses the electrode to extend through the gas channel (annular passage **34,** see figures 3 and 6) and for the electrode to be adapted to communicate with a source of electrosurgical energy (RF energy).

Regarding claim 15, Broadwin et al broadly discloses the electrode to be adjustable within the gas supply channel. The disclosure by Broadwin et al of the threaded engagement of the tool (**20**) with the connecting member (**38**) is capable of acting as such (see col. 4, lns. 8-20). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention that the removable engagement can function to allow for axial movement within the channel resulting in an adjustable electrode position.

12. Claims 1, 10-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Stoddard et al (US Pat No. 6,214,017 B1) in view of Schoenman et al (US Pat. No. 6,402, 748 B1).

Regarding claim 1, Stoddard et al discloses an electrosurgical instrument (apparatus **10**) containing a handpiece (handpiece **12**) and a tool member (tool **44**) having a proximal end adapted to engage an acoustic vibrator and having a distal tool tip (tip **22**). Stoddard et al further discloses the tool member to be formed from an electrically conductive material (see col. 6, lns, 30-31) and for the tool member to define an aspiration channel (see col. 5 , lns. 3-8). Additionally, Stoddard et al discloses a nosecone (flue **18**) defining an inner housing. Stoddard et al fails to disclose the inclusion of a switch to control electrosurgical energy mounted on the nosecone. Schoenman et al discloses a handheld electrosurgical device possessing a switch disposed on the housing of the device and a seal about the housing and switch assembly contained on the housing. Schoenman et al further discloses the seal to be elastomeric and formed of a dielectric material (see col. 5, ln. 18-35). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to include a switch and a seal as disclosed by Schoenman et al on the electrosurgical instrument of Stoddard et al to allow for an electrosurgical instrument with a sealed switch. The combination is readily allowed due to the old and well known idea of a switch being disposed on the body of an electrosurgical instrument as seen in the Schoenman et al reference as well as the various seal molding ideas disclosed.

Regarding claim 10, Stoddard et al discloses a tool member to include a coupling member (connecting member **42**) and a removable tip (tool **44**, tip **22**), the coupling member releasably engaging the tip and acoustic vibrator (see col. 7, lns 12-13).

Regarding claim 11, Stoddard et al discloses an aspiration conduit (aspiration line **24**) and for the coupling member (connecting member **42**) to include a bore for receiving the aspiration conduit (see figure 12, connecting member **42**, bore hole). Stoddard et al further discloses the nosecone (flue **16**, cap **62**) to include a bored to facilitate insertion of the aspiration conduit into the aspiration bore (see col. 8, lns. 62-67, figure 15).

Regarding claim 12, Stoddard et al discloses a locking member (coupling **64**) supported on the distal end of the aspiration conduit and for the nosecone to include an engagement member (see figure 15, cap **62** and col. 4, lns. 50-56), the locking member allowing for releasable engagement of the aspiration conduit.

Conclusion

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Soring (US Pat. No. 5,626,560) discloses a diathermic device capable of providing electrosurgical energy to an ultrasonic application means and conductive electrode. This device further allows for aspiration, irrigation and inert gas supply to the application target area.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to RONALD J. HUPCZEY, JR. whose telephone number is

(571)270-5534. The examiner can normally be reached on Monday through Friday (7:30 A.M. to 5:00 P.M. EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe H. Cheng can be reached on 571-272-4433. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/R. J. H./
Examiner, Art Unit 4116
6/20/2008

/Joe H Cheng/
Supervisory Patent Examiner
Art Unit 4116